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09/645,593	08/25/2000	Sarita Chaudhary	9369-151/MG	4599

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 11/20/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/645,593

Applicant(s)

CHAUDHARY ET AL.

Examiner

David H Kruse

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group IV, claims 1-23 and SEQ ID NO: 8, in Paper No. 11, filed 9 August 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. This application contains claimed SEQ ID NOs drawn to inventions nonelected without traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144). See MPEP § 821.01.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Information Disclosure Statement

4. The information disclosure statement filed 15 August 2001 has been considered, a copy of which is attached hereto.

Drawings

5. The drawings in this application are objected to by the Draftsperson as informal. See the attached PTO-948 form. Applicant is reminded that correction of the drawings

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cannot be held in abeyance, and that formal drawings are required in response to this Office Action as outlined in 37 CFR § 1.85(a). Failure to take corrective action within the set period will be considered non-responsive to this Office Action.

Claim Objections

6. Claims 5, 11, 14, 15, 16, 22 and 23, are objected to because of the following informalities:

At claims 5, 11, 14 (b)-(e) and claim 15 (a) (1)-(4), the phrase "a nucleic acid sequence of" should read -- the nucleic acid sequence of --. In addition, said claims are directed to non-elected inventions and should be amended accordingly in response to this Office action.

At claims 14 and 15, line 1, the phrase "isolated...nucleic acid sequence" is an improper designation of a composition of matter, the phrase -- isolated...nucleic acid molecule -- is suggested, and claim 16, line 3, should be amended accordingly.

Appropriate correction is required.

At claims 22 and 23, the phrase "comprising a nucleic acid sequence" should read -- comprising the nucleic acid sequence --.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-23 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims an isolated nucleic acid molecule capable of directing seed-specific expression in a plant comprising a nucleic acid sequence that has substantial sequence homology to SEQ ID NO: 8 or is an analog of SEQ ID NO: 8, or hybridizes to a nucleic acid sequence under stringent hybridization conditions to a nucleic acid molecule having the sequence of SEQ ID NO: 8, and chimeric genes and transgenic flax plants comprising said isolated nucleic acid molecules and methods of expressing a nucleic acid of interest in flax seeds. Applicant also claims a method of expressing a nucleic acid sequence of interest in flax seed comprising using a seed-specific promoter obtained from flax and transgenic plants produced therefrom.

Applicant describes an isolated nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 8, a chimeric construct comprising said molecule and transgenic plants comprising said construct (Example 6 on pages 30-34 of the specification). Applicant describes a nucleic acid construct comprising a fragment from bases 1 to approximately 2040 shown in SEQ ID NO: 8, and that said fragment has seed-preferred promoter activity when operably linked to a heterologous coding region and is expressed in a transgenic plant (see page 31 of the specification and Figure 10).

Applicant does not describe other isolated nucleic acid molecules that have substantial sequence homology to SEQ ID NO: 8 or is an analog of SEQ ID NO: 8, or hybridizes to a nucleic acid sequence under stringent hybridization conditions to a nucleic acid molecule having the sequence of SEQ ID NO: 8 as broadly claimed.

Hence it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See *Fiers* 25 USPQ 2d (CAFC 1993) at 1606 that states “[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself”.

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

9. Claims 1-23 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule comprising a nucleic acid sequence comprising bases 1-2040 of SEQ ID NO: 8 having seed-preferred promoter activity, does not reasonably provide enablement for a nucleic acid homologue, a nucleic acid analog or an isolated nucleic acid molecule that hybridizes under stringent hybridization conditions to a nucleic acid molecule having the sequence of SEQ ID NO: 8, compositions comprising same or method of using same. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims an isolated nucleic acid molecule capable of directing seed-specific expression in a plant comprising a nucleic acid sequence that has substantial sequence homology to SEQ ID NO: 8 or is an analog of SEQ ID NO: 8, or hybridizes to a nucleic acid sequence under stringent hybridization conditions to a nucleic acid molecule having the sequence of SEQ ID NO: 8, and compositions comprising said isolated nucleic acid molecules and methods of using same. Applicant also claims a method of expressing a nucleic acid sequence of interest in flax seed comprising using a seed-specific promoter obtained from flax and transgenic plants produced therefrom.

Applicant teaches an isolated nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 8, a chimeric construct comprising said molecule and transgenic plants comprising said construct (Example 6 on pages 30-34 of the specification). Applicant teaches a nucleic acid construct comprising a fragment from bases 1 to approximately 2037 shown in SEQ ID NO: 8, and that said fragment has seed-preferred promote activity when operably linked to a heterologous coding region and expressed in a transgenic plant (see page 31 of the specification and Figure 10).

Applicant does not teach other isolated nucleic acid molecules that have substantial sequence homology to SEQ ID NO: 8 or is an analog of SEQ ID NO: 8, or hybridizes to a nucleic acid sequence under stringent hybridization conditions to a nucleic acid molecule having the sequence of SEQ ID NO: 8 as broadly claimed.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has provided limited guidance for isolating and using homologues and analogs of the promoter sequence taught in SEQ ID NO: 8. The instant claims are directed to seed-specific promoter sequences isolated from flax, or broadly to any seed-preferred promoter sequence that would be an analog of the promoter sequence taught in SEQ ID NO: 8. Applicant does not teach a seed-specific promoter obtained from flax that is responsive to change in lighting conditions, change in temperature or change in concentration of a chemical agent at claim 3. The art for defining developmentally regulated promoter sequences is unpredictable, and one of skill in the art cannot readily recognize a seed-preferred promoter sequence by its nucleic acid sequence, what is required is empiric experimentation. Chamberland *et al* (1992, Plant Molecular Biology, 19:937-949) teach that in the soybean β -conglycinin seed storage protein promoter sequence, certain mutations have a minimal effect on promoter activity in transgenic plants while other mutations or combinations thereof can have substantial effects on seed-preferred promoter activity (see Figure 2 and Table 1 on page 941). Such mutant would bind under stringent conditions to the wild type promoter sequence, would be

homologues and would also be analogs thereof. Donald *et al* (1990, EMBO J. 9:1717-1726) in a mutational analysis of the *Arabidopsis rbcS-1A* promoter found that the effect of a particular mutation was dependent on promoter fragment length (paragraph spanning pg 1723-1724). Hence, given the limited guidance by Applicant, the unpredictability of the art and the teachings of the art at the time of Applicant's invention, it would have required undue trial and error experimentation to screen through a myriad of homologues, analogues and nucleic acid molecules that hybridize under stringent conditions to a nucleic acid molecule having the sequence of SEQ ID NO: 8 to determine which nucleic acid molecules have seed-preferred promoter activity and/or are responsive to change in lighting conditions, change in temperature or change in concentration of a chemical agent, even those nucleic acid molecules obtained from flax as broadly claimed.

In view of Applicant's use of the phrase "seed-specific promoter" in the instant claims, the Examiner puts forth the following argument. It is the Examiner's opinion that the phrase "seed-specific promoter" (a) unduly limits the claimed invention and (b) Applicant has failed to enable the limitation "seed-specific promoter" for the following reasons. Said phrase implies that the claimed promoter is only active in seeds of a plant. It is recognized by the art that as directed to promoters, "specific" is really "preferred" wherein activity is preferential to a specific plant tissue, but that activity does occur in other tissues, just at a much lower level. In the instant case, the teachings of Applicant clearly show that the taught promoter activity of the sequence shown in SEQ ID NO: 8 is seed-preferred, but that chimeric constructs, using a GUS coding sequence,

does occur in other tissues, in particular the buds of a transgenic plant which are anatomically modified stems comprising modified leaves (see Figure 10). Thus, it is the Examiner's recommendation that Applicant amend the phrase "seed-specific promoter" to read -- seed-preferred promoter --.

10. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claims 2-5, 8, 9, 11, 12 and 14-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite because it is unclear to what the claim is referring as to "characteristic conferred by said seed-specific promoter" is "conferred to said non-native nucleic acid sequence". In the instant case, it is unclear that a promoter confers any expression characteristic to its associated coding region. It is in fact the promoter that comprises an expression characteristic and not the associated native nucleic acid sequence. Expression of the coding sequence is a consequence of the expression characteristic of the promoter region. Claim 3 is also indefinite for the reason given for claim 2.

Claim 4 is rejected as indefinite for being in improper Markush format. The Office recommends the use of the phrase "selected from the group consisting of..." with the use of the conjunction "and" rather than "or" in listing the species. See MPEP § 2173.05(h). In the instant case it is unclear if Claim 4 is listing a group of species from

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which one would choose one, or if any combination of species are encompassed, hence it is unclear what the metes and bounds of the claimed invention are.

At claims 5, 11, 14 and 15, the phrases “has substantial sequence homology to”, “is an analog of a nucleic acid sequence” and “hybridizes...under stringent hybridization conditions” are indefinite for the following reasons; The phrase “sequence homology” is art recognized as being qualitative and not quantitative, and asserts a type of relationship between two or more things (see Reeck *et al* 1987, Cell 50:667). Also, “substantial” is a relative term and hence the metes and bounds of the phrase are unclear. The term “analog” is indefinite because it is unclear what the metes and bounds of an “analog” are in the instant claim, it is unclear if “analog” means any seed-specific promoter or in fact any promoter. The phrase “hybridizes...under stringent hybridization conditions” is indefinite because said phrase is relative, there being many degrees of stringent hybridization conditions, all of which must be defined in terms of salt concentration, binding and washing temperature and binding and washing times.

Claims 8 and 9 are indefinite for the reasons given supra for claims 2 and 3, briefly, that a promoter does not confer an expression characteristic to an associated coding region.

Claim 15 is indefinite because at 15(a)(2), for example, said subsection is further limiting itself and hence does not state the metes and bounds of the claimed invention. Specifically, it is unclear how the nucleic acid sequence at 15(a)(2) could hybridize to the nucleic acid sequence of 15(a)(2), itself, said nucleic acid sequence requiring a complementary sequence to hybridize. Subsections (a)(2)-(4), limit themselves, but

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appear to further limit 15(a)(1), which designates a specific nucleic acid sequence. The phrase -- the nucleic acid sequence of (a)(1) is suggested --, at subsections (a)(2)-(4).

Those claims not specifically addressed in the instant rejection are also rejected as indefinite because said claims do not obviate the indefiniteness of the claim or claims upon which they depend.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-3, 5-9 and 11-23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Jain *et al* (WO 98/18948, published 7 May 1998).

Jain discloses two seed-preferred promoter sequences operably associated with steroyl-(acyl-carrier-protein)-desaturase (SAD) coding sequences isolated from flax (see SEQ ID NO: 3 and 4). Said coding sequences alter the fatty acid composition of seeds (see page 3, 2nd paragraph). Jan discloses chimeric constructs and plant transformation vectors comprising said promoter sequences operably linked to heterologous sequences of interest, and tobacco and canola plants transformed therewith, and that said promoter preferentially expresses the operably linked coding sequence in the seeds of the transgenic plant (see Figures 8 & 10). Jain discloses that the associated SAD coding sequences can be used to modify the levels of saturated fatty acids in heterologous plants such as rapeseed and soybean (page 7, last

paragraph). Jain also discloses that the seed-preferred promoter sequences can be operably linked to heterologous coding sequence to alter the levels of different types of fatty acids in flax (see page 8, 2nd paragraph). The seed-preferred promoter sequences of Jain would have been considered homologous, that is evolutionarily related, to the promoter in SEQ ID NO: 8 disclosed by Applicant, and would also be considered an analog, that being both the promoter sequences of Jain and that of Applicant are flax seed-preferred promoters. Hence, Jain has previously disclosed all of the claim limitations.

Conclusion

14. No claims are allowed.

15. Claims 4 and 10 appear to be free of the prior art, which neither teaches nor fairly suggests a seed-specific promoter isolated from flax that is operably associated with an oleosin gene, a 2S storage protein gene, or a legume-like seed-storage protein gene.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



David H. Kruse, Ph.D.
13 November 2002

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